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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,462	02/27/2002	Vincent Fischetti		5777

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,462	FISCHETTI ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Request for Continued Examination received on January 20, 2004 and Amendments/Remarks received on April 1, 2004 is acknowledged.

Status of Pending Claims

Claims **27-38** are pending in this application. Claims 1-14 stand cancelled per Preliminary Amendment of February 27, 2002 and claims 15-26 stand cancelled per Amendments/Remarks of August 1, 2002. Applicant cannot re-enter previously cancelled claims 15-26.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27 and 37-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 and 10-11 of copending Application No. 10/012032. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both applications contain similar subject matter.

Instant application claims a suppository comprising: an effective amount of at least one lytic enzyme encoded a specific bacteriophage specific for Listeria, Salmonella, E. coli, and

Campylobacter and a suppository carrier. Claims 37-38 are directed to a concentration of 100 to 100,000 and 10,000 respectively.

Co-pending application '032 claims a composition comprising an effective amount of at least one lytic enzyme encoded a bacteriophage for a specific bacteria and a pharmaceutically acceptable carrier.

Therefore, co-pending application '032 recites the generic claim wherein it is generic for the lytic enzyme containing the bacteriophage and generic for the carrier. Note that the intended mode of administration, i.e. "carrier for topical application" in '032 does not hold patentable weight for a product claims unless the mode of administration is claimed in structural terminology. Thus, instant application is fully encompassed by application '032 since it is directed to the species wherein it claims a specific lytic enzyme with a specific bacteriophage and a specific carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27-29 and 35-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 27, 32-33, 36-38, 42-47, 52-53, 77, 95, 115, 123-124 of copending Application No. 10/083462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both applications contain similar subject matter.

Instant application claims a suppository comprising: an effective amount of at least one lytic enzyme encoded a specific bacteriophage specific for Listeria, Salmonella, E. coli, and Campylobacter and a suppository carrier. Claims 28-29 are directed to maintaining the pH of the

composition between 4-9 and 5.5-7.5 respectively, with a buffer. Claims 36 is directed a lyophilized enzyme. Claims 37-38 are directed to a concentration of 100 to 100,000 and 10,000 respectively.

Co-pending application '462 claims 27, 38, 47, 77, 95, and 115 are directed to a composition comprising an effective amount of at least one lytic enzyme encoded a bacteriophage selected from chimeric and shuffled enzymes and for a specific bacteria and a pharmaceutically acceptable carrier. Dependent claims 32-33 and 44 respectively are directed to maintaining the pH of the composition between 4-9 and 5.5-7.5 respectively, with a buffer. Claims 35 is directed a lyophilized enzyme. Claim 36-37 and 45-46 respectively are directed to a concentration of 100 to 100,000 and 10,000. Claim 42 is directed to the instantly claimed bacteria. Claim 43 is directed to a carrier selected from a Markush group containing instant suppository.

Therefore, co-pending application '462 recites the generic claim wherein it is generic for the lytic enzyme containing the bacteriophage and generic for the carrier. Note that the intended mode of administration, i.e. "carrier suitable for delivery " for the mouth, nasal, skin, vagina, digestive tract, and teeth in '462 does not hold patentable weight for a product claim unless the mode of administration is claimed in structural terminology. Thus, instant application is fully encompassed by application '462 since it is directed to the species wherein it claims a specific lytic enzyme encoded by a specific bacteriophage and a specific carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 27 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because the both applications contain similar subject matter.

Instant application claims a suppository comprising: an effective amount of at least one lytic enzyme containing a specific bacteriophage specific for Listeria, Salmonella, E. coli, and Campylobacter and a suppository carrier.

US patent '097 claims an enteric coated composition comprising an effective amount of at least one lytic enzyme containing a bacteriophage selected and for a specific bacteria Listeria, Salmonella, E. coli, and Campylobacter and a carrier.

Therefore, US patent '097 recites the generic claim wherein the carrier and claims the same bacteria. Note that the preamble, i.e. "an enteric coated pill" does not hold patentable since it does not provide a structural limitation in the body of the claim and merely is in the preamble. Thus, instant application is fully encompassed by US patent '097 since it is directed to the same bacteria and a specific carrier.

Miscellaneous Remarks

The examiner has done a preliminary search to identify double patenting issues and as set forth the rejections. However, due to the numerous applications submitted by applicant, the applicant is requested to identify other applications that applicant has filed that might contain double patenting issues.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27-38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is recites the limitation "said suppository enema" in line 2. However, applicant has amended the claims to remove "enema" in line 1 and therefore "said enema" does not have sufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-30 and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in view of Liu et al (5374545).

Miyauchi teaches preparations containing various active agent. Example 7 teaches a rectal suppository containing lysozyme chloride for the gastrointestinal tract. The reference teaches the use of EDTA for increasing the absorption of the medicine (col. 5, lines 4-7). The reference teaches the pH range for the composition (note examples).

Miyauchi et al do not teach specify that the lytic enzymes kill the instant bacteria.

Liu et al teach the effectiveness a lytic enzyme to be useful as a antibacterial agent, the enzyme must be capable of degrading a broad spectrum of bacteria that cause infections. See column 2, lines 19-25. Liu et al teach lytic enzymes that are capable of depolymerizing bacterial

cell walls to prevent the growth of target microorganisms such as E.coli, Salmonella, and Campylobacter (col. 1, lines 21-30 and column 5-6). E.coli, Salmonella, and Campylobacter are recognized as food borne pathogens, when the viable bacteria are ingested by the host, which then grow and establish themselves in the host, resulting in infection and illness (col. 5, lines 55-65). Additionally, the lytic enzymes may be formulated into solid or liquid preparations, wherein the solid preparation contains a lyophilized enzyme. See column 7, lines 14-35. The enzymes are taught for use in the healthcare industry and its incorporation into solid enzyme preparations where the enzyme is lyophilized (col. 1, line 66 and col. 7, line 15). Liu et al teach Liu teaches the lytic enzyme functions at a pH of 7 (col. 2, line 65). Liu discloses that food borne infection is caused by the ingestion of viable bacteria, which then grow and establish themselves in the host, resulting in illness (col. 5, lines 55-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Miyauchi et al and Liu et al and incorporate Liu's lytic enzymes in Miyauchi's suppository base. One would have been motivated to do so since Liu et al teach effective lytic enzymes that provide target killing of instant bacteria which cause food poisoning. Therefore, one would be motivated to use Liu et al's lytic enzymes if one desired to treat food borne bacterial infections caused by E.coli, Salmonella, or Campylobacter.

In the absence of showing the criticality of using citrate-phosphate buffer versus phosphate buffer, it is deemed obvious to one of ordinary skill in the art to use either since the prior art teaches the instant pH using a phosphate buffer.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyauchi (4900730) in view of Liu et al (5374545) in further view of Goldstein et al (5861295).

As set forth above, the references teach compositions containing lysozymes.

The references do not teach the use of instant reducing reagent.

Goldstein et al teach the method of producing thermostable enzymes. The reference teaches a filtration buffer solution containing EDTA and the dithothreitol. The reference discloses that it is known to one of ordinary skill in the art to substitute buffer solutions as long as they have the equivalent effect (col. 8, lines 35-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Goldstein et al and use dithiothreitol. One would be motivated to do so since Goldstein et al teach buffer solutions, which contains both EDTA and dithiothreitol and state such buffer solution are known to one of ordinary skill in the art. Thus, the utilization of known and conventionally utilized buffer solutions is deemed prima facie obvious.

Response to Arguments

Applicant argues that the prior art enzymes destroy all bacterial flora and instant invention is very specific for the bacterial species and does not kill the "good bacteria" in the gut. Thus, applicant argues that the instant invention does not cause diarrhea. Applicant argues that the instant lytic enzyme is specific for a specific bacteria and is not known in the art.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that the feature argued by applicant that the suppository does not kill "good bacteria" is not recited in the claims, thus this argument is moot.

Secondly, the examiner points out that the Liu et al also teach targeting instant microorganisms with a lytic enzyme. If applicant intends to claim a specific lytic enzyme

encoded for a bacteriophage that is not known in the art, then the applicant must claim the ATTP deposit number to differentiate the instant claims over the prior art.

Thus, the claims are rejected under obviousness.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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